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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,465	11/23/2005	Andrew Heath	5585-71231-01	4050

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,465	HEATH ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 9-29* is/are pending in the application.

4a) Of the above claim(s) *11-18 and 22-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,10 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-4 and 9-29 are pending.

Claims 5-8 and 30-50 have been canceled previously.

2. Applicant's election of the species of Group B, drawn to an adjuvant comprising a conjugate of an anti-CD40 antibody and at least one antigen, wherein the antigen is a ganglioside such as MUC-1 (as it reads on claims 1-4, 9-10 and 19-21) without traverse in the Response To The Office Action, filed 03/28/2008, is acknowledged.

Claims 11-18 and 22-29 have been withdrawn as being drawn to non-elected species.

Given applicant's election of ganglioside and MUC-1 and applicant's Response indicating that the election reads on claims 9 and 10;
claims 1-4, 9-10 and 19-21 are being acted upon as they read upon the elected invention.

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. The effective filing date of the instant claim is deemed to be the filing date of the priority application United Kingdom 0228796.9 filed 12/11/2002.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:
A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4 and 9-10 are rejected under 35 U.S.C § 102(b) as being anticipated by Heath (CA 2,207,246) (see entire document).

Heath teaches the use of anti-CD40 antibodies, including monoclonal and humanized antibodies and binding fragments thereof (e.g. see page 7, paragraphs 3-4; page 9, paragraphs 3-4; page 12, paragraphs 3-4)) as adjuvants in the construction of vaccines to T-cell independent and dependent antigens (e.g., see page 5, paragraph 1; page 6, paragraph 1; page 8, paragraph 4; page 9, paragraphs 6-7; page 10, paragraph 1), including recombinant, co-joined and cross-linked formulations (e.g., see pages 5-12, including page 9, paragraph 7; page 10, paragraphs 2-5; page 12, paragraph 1; pages 22-23, overlapping paragraph).

In consideration of the differences between the referenced and claimed characteristics of the oligomeric complex consisting of one to approximately five antibodies per complex, the burden is on the applicant to establish a patentable distinction between the claimed and referenced anti-CD40 adjuvants cross-linked or produced as a fusion protein with T cell independent or T cell dependent antigens.

Also, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

8. Claims 1-4 and 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Heath (US 2002/0136722) (see entire document, including Claims).

Heath teaches adjuvants comprising anti-CD40 antibodies and antigen, wherein the antigen and adjuvant can be cross-linked together (e.g., see paragraph [0029]) or produced as a chimeric fusion protein (e.g., see paragraph [0035]) and the antigen can be T-cell dependent or T-cell independent (e.g., see paragraph [0017]) (see entire document, including Summary of the Invention and Examples on pages 4-10 and Claims).

Given the prior art teachings of anti-CD40 antibodies and antigens as linked or fusion proteins with the same or substantially the same properties as claimed;
the claimed structural and functional limitations would be inherent properties of the referenced anti-CD40 adjuvants cross-linked or produced as a fusion protein with T cell independent or T cell dependent antigens.

Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons.

In consideration of the differences between the referenced and claimed characteristics of the oligomeric complex consisting of one to approximately five antibodies per complex,
the burden is on the applicant to establish a patentable distinction between the claimed and referenced anti-CD40 adjuvants cross-linked or produced as a fusion protein with T cell independent or T cell dependent antigens.

Also, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

9. Claims 1-4, 9-10 and 19-21 are rejected under 35 U.S.C § 102(e) as being anticipated by Steinaa et al. (U.S. Patent No. 7,005,498) (see entire document).

Steinaa et al. teach the use of suitable targeting adjuvant including anti-CD40 antibodies (e.g., see column 23, paragraph 2) and T cell dependent and T cell independent antigens (e.g., see columns 28-34), such as the mucins, including MUC-1 (e.g., see column 32), wherein the adjuvants can be cross-linked with antigens (e.g., see Polypeptide Vaccination on columns 20-24, including column 22, paragraphs 1 and 5) (see entire document).

In consideration of the differences between the referenced and claimed characteristics of the oligomeric complex consisting of one to approximately five antibodies per complex,
the burden is on the applicant to establish a patentable distinction between the claimed and referenced anti-CD40 adjuvants cross-linked or produced as a fusion protein with T cell independent or T cell dependent antigens.

Also, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

10. Claims 1-4, 9-10 and 19-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Heath (CA 2,207,246) in view of Steinaa et al. (U.S. Patent No. 7,005,498).

Heath teaches the use of anti-CD40 antibodies, including monoclonal and humanized antibodies and binding fragments thereof (e.g. see page 7, paragraphs 3-4; page 9, paragraphs 3-4; page 12, paragraphs 3-4) as adjuvants in the construction of vaccines to T-dependent antigens (e.g., see page 5, paragraph 1; page 6, paragraph 1; page 8, paragraph 4; page 9, paragraphs 6-7; page 10, paragraph 1); including recombinant, co-joined and cross-linked formulations (e.g., see pages 5-12, including page 9, paragraph 7; page 10, paragraphs 2-5; page 12, paragraph 1; pages 22-23, overlapping paragraph).
Heath differs from the claimed methods by not disclosing the gangliosides or Muc-1 as the antigen of interest.

Steinaa et al. teach the use of suitable targeting adjuvant including anti-CD40 antibodies (e.g., see column 23, paragraph 2) and T cell dependent and T cell independent antigens (e.g., see columns 28-34), such as the mucins, including MUC-1 (e.g., see column 32), wherein the adjuvants can be cross-linked with antigens (e.g., see Polypeptide Vaccination on columns 20-24, including column 22, paragraphs 1 and 5) (see entire document).

Given the prior art teachings of the applicability of anti-CD40 antibody based adjuvant – vaccine constructs to induce immune response to T cell dependent and independent antigens, as taught by Heath and Steinna et al.,
including tumor antigens such as the mucins, as taught by Steinna et al.;
it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the particular tumor antigen MUC-1 into such constructs to generate immune responses to tumor antigens of interest such as the particular MUC-1 in the treatment of patients with certain tumors at the time the invention was made. Similarly, one of ordinary skill in the art would have been motivated to substitute the particular constructs taught by Heath, given the efficacy of the anti-CD40 adjuvant-vaccine constructs taught by Heath and Steinna. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In consideration of the differences between the referenced and claimed characteristics of the oligomeric complex consisting of one to approximately five antibodies per complex,
the burden is on the applicant to establish a patentable distinction between the claimed and referenced anti-CD40 adjuvants cross-linked or produced as a fusion protein with T cell independent or T cell dependent antigens.

Note, too, that both Heath and Steinna et al. teach anti-CD40 antibodies as well as antigen binding fragments thereof.

Also, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).
"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 550 U.S., 2007 U.S. LEXIS 4745, 2007 WL 1237837, at *12 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

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